Notice of Allowability	Application No.	Applicant(s)	
	09/994,164	KELLER ET AL.	
	Examiner	Art Unit	
	Robert A. Wax	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment filed August 11, 2006*.

2. ☒ The allowed claim(s) is/are *1, 26, 27, 36, 37 and 40*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Howard Lee on August 31, 2006.

The application has been amended as follows:

Replace the first paragraph in the specification with the following:

- - -This application is a Reissue of Serial No. 09/302,217, filed April 29,1999, now US Patent 6,262,019, which claims benefit of provisional application 60/083,661, filed April 30, 1998.- - -

Replace the existing claim set with the following:

1. A composition of matter, which comprises in admixture; N-acetylcysteine[;], N-acetyl-d-glucosamine and vitamin C whereby the amount of vitamin C is in an amount of at least 1000 mg. or greater to facilitate the absorption of N-acetylcysteine across the cellular membrane; and, a pharmaceutically acceptable carrier for oral administration.

[2. The composition of claim 1 further comprising one or more of the following substances from the group consisting of alpha-lipoic acid, sylmarin, quercitin, l-glutamine, a probiotic, and dietary protein.]

[3. The composition of claim 1 further comprising alpha-lipoic acid, sylmarin, quercitin, l-glutamine, and a probiotic.]

[4. The composition of claim 3 further comprising dietary protein.]

[5. The composition of claim 1 further comprising flavorants.]

[6. The systematic administration of a pharmaceutically effective amount of the composition according to claim 1 to a mammal suffering from low glutathione levels, to stimulate the natural production of glutathione in the biologically active cells of the mammal.]

[7. The systemic administration of a pharmaceutically effective amount of the composition according to claim 2 to a mammal suffering from hepatitis, to stimulate the natural production of glutathione in the biologically active cells of the mammal.]

[8. The systemic administration of a pharmaceutically effective amount of the composition according to claim 2 to a mammal suffering from HIV, to stimulate the natural production of glutathione in the biologically active cells of the mammal.]

[9. The systemic administration of a pharmaceutically effective amount of the composition according to claim 2 to a mammal suffering from allergies, to stimulate the natural production of glutathione in the biologically active cells of the mammal and to promote the shift of the T-cell balance from TH2 to TH1 and decrease levels of IgE.]

10. The systemic administration of a pharmaceutically effective amount of the composition according to claim 2 to a mammal to decrease serum cholesterol and triglycerides.]

[11. The systemic administration of a pharmaceutically effective amount of the composition according to claim 2 to a mammal suffering from one or more of the following illnesses from the group consisting of chronic viral infections: HIV, hepatitis C, chronic fatigue, immunodeficiency syndrome, immune deficiencies, cancer, B-cell malignancies, including lymphomas, chronic leukemia, myeloma, Waldenstrom's and MGUS to improve immune defense productions and thereby mitigate the progression of the illnesses to thereby limit fatigue.]

[12. The systemic administration of a pharmaceutically effective amount of the composition according to claim 2 to a mammal to decrease fatigue.]

[13. The systemic administration of a pharmaceutically effective amount of the composition according to claim 2 to a mammal to decrease the biologic effects of stress.]

[14. The systemic administration of a pharmaceutically effective amount of

the composition according to claim 2 to a mammal to increase energy and improve physical performance.]

[15. Administration according to claim 6 wherein a pharmaceutically effective amount is 0.1 mg/kg to about 50 mg/kg of body weight of the mammal, daily.]

[16. Administration according to claim 6 wherein a pharmaceutically effective amount is 0.5 mg/kg to about 25 mg/kg of body weight of the mammal, daily.]

[17. The systemic administration of a pharmaceutically effective amount of the composition according to claim 2 to a mammal suffering from low glutathione levels, to stimulate the natural production of glutathione in the biologically active cells of the mammal.]

[18. The systemic administration of a pharmaceutically effective amount of the composition according to claim 3 to a mammal suffering from low glutathione levels, to stimulate the natural production of glutathione in the biologically active cells of the mammal.]

[19. The systemic administration of a pharmaceutically effective amount of the composition according to claim 1 to a mammal suffering from low glutathione levels, to stimulate the natural production of glutathione in the biologically active cells of the mammal and reduce symptoms of diseases caused by excess unneutralized free radicals.]

[20. The systemic administration of a pharmaceutically effective amount of the composition according to claim 2 to a mammal suffering from low glutathione levels, to stimulate the natural production of glutathione in the biologically active cells of the mammal and reduce symptoms of diseases caused by excess unneutralized free radicals.]

[21. The systemic administration of a pharmaceutically effective amount of the composition according to claim 3 to a mammal suffering from low glutathione levels, to stimulate the natural production of glutathione in the biologically active cells of the mammal and reduce symptoms of diseases caused by excess unneutralized free radicals.]

[22. The systemic administration of a pharmaceutically effective amount of the composition according to claim 19, wherein the disease is a member of the group consisting of pulmonary oxygen toxicity, adult respiratory distress syndrome, broncopulmonery dysplasia, sepis syndrome, Parkinson's disease, encephalitis, endotoxemia, anoxia induced neuronal damage, ischemic reperfusion injury, inflammatory diseases, systemic lupus erythematosis, myocardial infarction, stroke, traumatic hemorrhage, spinal cord trauma, Crohn's

disease, rheumatoid arthritis, diabetes, cataract formation, uvetis, emphysema, gastric ulcers, oxygen toxicity, neoplasia, undesired cell apoptosis, radiation sickness.]

[23. The systemic administration of a pharmaceutically effective amount of the composition according to claim 20, wherein the disease is a member of the group consisting of pulmonary oxygen toxicity, adult respiratory distress syndrome, broncopulmonery dysplasia, sepis syndrome, Parkinson's disease, encephalitis, endotoxemia, anoxia induced neuronal damage, ischemic reperfusion injury, inflammatory diseases, systemic lupus erythematosis, myocardial infarction, stroke, traumatic hemorrhage, spinal cord trauma, Crohn's disease, rheumatoid arthritis, diabetes, cataract formation, uvetis, emphysema, gastric ulcers, oxygen toxicity, neoplasia, undesired cell apoptosis, radiation sickness.]

[24. The systemic administration of a pharmaceutically effective amount of the composition according to claim 21, wherein the disease is a member of the group consisting of pulmonary oxygen toxicity, adult respiratory distress syndrome, broncopulmonery dysplasia, sepis syndrome, Parkinson's disease, encephalitis, endotoxemia, anoxia induced neuronal damage, ischemic reperfusion injury, inflammatory diseases, systemic lupus erythematosis, myocardial infarction, stroke, traumatic hemorrhage, spinal cord trauma, Crohn's disease, rheumatoid arthritis, diabetes, cataract formation, uvetis, emphysema, gastric ulcers, oxygen toxicity, neoplasia, undesired cell apoptosis, radiation sickness.]

[25. The systemic administration of a pharmaceutically effective amount of the composition according to claim 1 to a mammal, to promote the natural production of glutathione in the biologically active cells of the mammal which accelerates the detoxification of ethanol and alleviates symptoms associated with excessive ethanol imbibation.]

26. The composition of claim 1 further comprising a probiotic, said probiotic for promoting the breakdown and absorption of nutrients, the elimination of toxins and to inhibit the growth of harmful bacteria in the gastrointestinal tract, thereby facilitating the absorption of N-acetylcysteine into the gastrointestinal tract.

27. The [probiotic] composition of claim [1] 26, wherein said probiotic [is a composition of "healthy bacteria" containing] comprises one or more [of said healthy] bacteria selected from the group [comprising] consisting of [bifidobacterium longum, bifidobacterium infantis, lactobacillus acidophilus, lactobacillus casei, lactobacillus rhamnosus, saccharomyces boulardi, propionibacteria and enterococci] *Bifidobacterium longum, Bifidobacterium*

infantis, Lactobacillus acidophilus, Lactobacillus casei, Lactobacillus rhamnosus, Saccharomyces boulardi, Propionibacteria and Enterococci.

[28. The composition of claim 2 further comprising 1-glutamine, said component being an essential dietary component to promote the support of gastrointestinal growth and function, thus facilitating the absorption of N-acetylcysteine through the gastrointestinal tract.]

[29. The composition of claim 4 wherein N-acetyl-d-glucosamine promotes the biosynthesis of mucosal glycoproteins which make up the glycocalyx, a layer of the gut mucosa which acts to protect the tissue of the gastrointestinal tract while providing a selectively absorptive surface, thus facilitating the absorption of N-acetylcysteine into the gastrointestinal tracts.]

36. A method of treatment comprising the step of systemically administering a pharmaceutically effective amount of the composition according to claim 1 to a mammal suffering from low glutathione levels, to stimulate the natural production of glutathione in the biologically active cells of the mammal and reduce symptoms of diseases caused by excess unneutralized free radicals.

37. The method of treatment according to claim 36, wherein the disease is a member of the group consisting of pulmonary oxygen toxicity, adult respiratory distress syndrome, bronchopulmonary dysplasia, sepis syndrome, Parkinson's disease, encephalitis, endotoxemia, anoxia induced neuronal damage, ischemic reperfusion injury, inflammatory diseases, systemic lupus erythematosis, myocardial infarction, stroke, traumatic hemorrhage, spinal cord trauma, Crohn's disease, rheumatoid arthritis, diabetes, cataract formation, uveitis, emphysema, gastric ulcers, oxygen toxicity, neoplasia, undesired cell apoptosis, and radiation sickness.

38. Canceled.

39. Canceled.

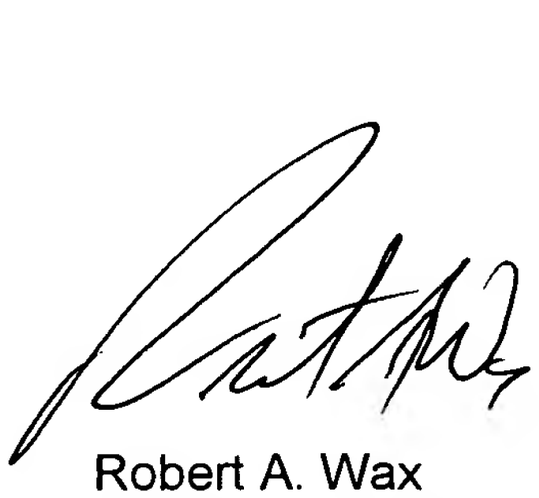
40. A method of promoting the biosynthesis of mucosal glycoproteins and/or facilitating the absorption of N-acetylcysteine into a gastrointestinal tract of a mammal, comprising the step of administering the composition of claim 1.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-

0623. The examiner can normally be reached on Monday through Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Robert A. Wax
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